FEB 17 2005

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SUMMARY OF SAFETY AND EFFECTIVENESS

K043411
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Sponsor: Resofix, Inc.
5349 Red Leaf Court
Oviedo, Florida 32765

Device: Resofix® Bioabsorbable Expansion Bolt

Classification Name: 21 CFR 888.3030 Fastener, Fixation, Biodegradable, Soft Tissue – Class II

Intended Use: The Resofix® Bioabsorbable Expansion Bolt is a single-use, sterile implant that is intended for use in the interference fixation of bone-tendon-bone and soft tissue grafts in anterior and posterior cruciate ligament reconstruction.

Device Description: The Resofix product is a two-shell bioabsorbable expansion bolt, consisting of two shell halves, forming an expanding dowel system, and a central expansion wedge. Insertion of the expansion wedge between the dowel halves results in expansion over the full length of the implant. When expanded, 2/3 of the implant cross-section is round and 1/3 is flat. The surface of the implant is designed to maximize contact and maintain implant position, both immediately after being inserted, as well as during the absorption period. The Resofix® Bioabsorbable Expansion Bolt shell halves and expansion wedge are injection molded poly-D,L-lactide (PDLLA, Resomer 208), which is substantially equivalent to the material used by Sulzer Orthopedics Ltd. in its Sysorb interference screws, previously approved by the U.S. FDA (K983592). Included in the system are associated preparation and implantation instruments, which are exempt Class I instruments, per 21 CFR 888.4540, "Orthopaedic Manual Surgical Instruments". The Resofix PDLLA implants are available in two sizes (8mm x 28mm and 10mm x 35mm) and the 10mm units are available in two expansion options (2.2mm for bone-tendon-bone grafts and 2.9mm for semitendinosus gracilis grafts).

Potential Risks: Possible adverse effects include –

- Loosening, cracking or fracture of the bolt, which may be caused by insufficient quality or quantity of base bone stock.
- Fracture of the femur or tibia caused by improper bolt placement.
- Laceration of the graft material, which would most likely be caused by operative instruments.
- Failure of the graft material to thrive following reconstruction. Although such a situation is rare, it may lead to dissolution of the graft material and recurrent instability of the knee.
- Acute or late infection and low grade synovitis.
- Cardiovascular disorders, including wound hematoma and thromboembolic disease.
- Tissue reaction, including macrophage and foreign body reactions adjacent to the bolt.

Substantial Equivalence:

The Resofix® Bioabsorbable Expansion Bolt is similar in material and purpose to the Arthrex Bio-Interference Screw which has been previously cleared by the Food and Drug Administration for interference fixation of bone-tendon-bone and soft tissue grafts in ACL and PCL reconstruction. Furthermore, biomechanical testing confirms that differences in design between the Resofix® Bioabsorbable Expansion Bolt and predicate device, do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2005

Mr. Carl Knobloch
Chief Operating Officer
Resofix, Inc.
5349 Red Leaf Court
Oviedo, Florida 32765

Re: K043411
Trade/Device Name: Resofix® Bioabsorbable Expansion Bolt
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: December 2, 2004
Received: December 13, 2004

Dear Mr. Knobloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K043411

Device Name: Resofix® Bioabsorbable Expansion Bolt

Indications for Use: The Resofix® Bioabsorbable Expansion Bolt is a single-use, sterile implant that is intended for use in the interference fixation of bone-tendon-bone and soft tissue grafts in anterior and posterior cruciate ligament reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043411